

Amendment and Response

Page 8 of 14

Serial No.: 10/808,124

Confirmation No.: 4531

Filed: 24 March 2004

For: MULTI-FORMAT SAMPLE PROCESSING DEVICES, METHODS AND SYSTEMS**Remarks**

The Office Action mailed October 15, 2007, has been received and reviewed. Claims 1, 3, 6, 7, 10, 13, 14, 17, and 18 having been amended, and claims 20-24 having been added, the pending claims are claims 1-24.

Claims 1, 3, 6, 7, 10, 13, 14, 17, and 18 have been amended to recite that the input chamber the output chamber, the primary process chamber, and, where recited, the secondary process chamber, of each process array are interconnected. Support for these amendments may be found in Applicants' specification, for example at page 12, lines 27-28; page 13, lines 15-27; and Figures 1, 2, 4, 5, 6B, and 10.

Claims 1, 6, 10, 13, and 17, have also been amended to recite a sample chamber that includes a rectangular body comprising four identifiable corners at the junctions of four identifiable sides and two major surfaces. Support for these amendments may be found in the specification at, for example, page 12, lines 3-14.

In addition, claims 1, 6, and 13 have been further amended to correct typographical errors.

Claims 20-24 have been added to further claim Applicants' disclosed invention. Support for the new claims may be found in Applicants' specification at, for example, page 13, lines 15-29; and Figure 2.

Reconsideration and withdrawal of the rejections in view of the following comments are respectfully requested.

Obviousness-Type Double Patenting Rejection

Claims 1-19 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,720,187. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

Amendment and Response

Page 9 of 14

Serial No.: 10/808,124

Confirmation No.: 4531

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For: MULTI-FORMAT SAMPLE PROCESSING DEVICES, METHODS AND SYSTEMS

The 35 U.S.C. §102 Rejections

Claims 1-19 were rejected under 35 U.S.C. §102(e) as being anticipated by Kellogg et al. (U.S. Patent No. 6,143,248). This rejection is respectfully traversed. In addition, Applicants continue to reserve the right, asserted in the Response filed 26 July 2007, to swear behind this document at a later date. In the interest of advancing prosecution of the application, however, Applicants continue to address this rejection on its merits.

For a claim to be anticipated under 35 U.S.C. § 102(e), each and every element of the claim must be found in a single prior art reference (M.P.E.P. §2131). It is submitted that Kellogg et al. do not teach each and every element of claims 1-19 as required for anticipation.

Independent claims 1, 6, 10, 13, and 17 each claim a sample processing device including, *inter alia*, a *rectangular body comprising four identifiable corners at the junctions of four identifiable sides and two major surfaces*, and a plurality of process arrays, wherein the output chambers of the process arrays of the plurality of process arrays are arranged in a *rectilinear grid array*. Further, independent claims 1, 6, 10, and 13 also claim that the input chambers of the plurality of process arrays are arranged in *rectilinear grid array*. Kellogg et al. fail to teach any of these features.

Rectangular body

In the present final Office Action (mailed October 15, 2007, hereinafter "final Office Action") it is indicated at page 4, lines 10-11, that "[t]he Office maintains figure 12 shows a rectangular body with plural processing arrays." Applicants disagree.

Figure 12 of Kellogg et al. shows "a platform of the invention comprising a metering capillary as described in Example 2" (Kellogg et al., col. 13, lines 34-36). The platform is described as a disk in Example 2 of Kellogg et al. (col. 32, lines 47-48, referencing the microplatform disks described in Example 1). Furthermore, Figure 12 itself depicts a curved platform edge and specifically discloses the feature of a *disk axis* (emphasis added). Thus, the body depicted in Figure 12 of Kellogg is a disk-shaped body which does not include four

Amendment and Response

Page 10 of 14

Serial No.: 10/808,124

Confirmation No.: 4531

Filed: 24 March 2004

For: MULTI-FORMAT SAMPLE PROCESSING DEVICES, METHODS AND SYSTEMS

identifiable corners at the junctions of four identifiable sides and two major surfaces as recited in claims 1, 6, 10, 13, and 17.

It is submitted that the only elements of Figure 12 of Kellogg et al. which may possibly be considered to have a rectangular *shape* are capillaries B, C or chambers D, E. None of these elements, however, anticipate a rectangular body comprising four identifiable corners at the junctions of four identifiable sides and two major surfaces. Applicants therefore request, in the event this rejection is maintained, that the Examiner provide direction to the portion of Kellogg et al. that teach a rectangular body as recited in claims 1, 6, 10, 13, and 17.

Rectilinear grid array

Kellogg et al. describe a centrifugal rotor having, *inter alia*, entry ports (A), fluid chambers (E), and overflow chambers (D) arranged in a circular arc on a circular disk. (Kellogg et al., col. 31, line 61; col. 32, line 46 to col. 33, line 61; Figure 12). In fact, it is noted in the Office Action mailed February 27, 2007 (and cited in the final Office Action, at page 3, line 13), that "[t]he Office maintains *all of the elements* taught by Kellogg et al. are arranged in a circular arc around the disk axis as shown in figure 12." (emphasis added). Applicants submit that this is an acknowledgment by the Office that Kellogg et al. do not teach output and input chambers of the process arrays of the plurality of process arrays that are arranged in a rectilinear grid array as recited in claims 1, 6, 10, 13, and 17.

In the final Office Action, in reply to Applicants' Response filed July 26, 2007, it is asserted that "Kellogg et al. teach a common input chamber 'A', a plurality of capillary chambers 'B', a second chamber 'E' all connected to an overflow chamber 'D'. The claimed '*rectangular body*' has been read on the structure shown on the rotor in figure 12 that is generally rectangular." (final Office Action, page 4, lines 15-18). The above statement provides no teaching as to the *arrangement* of elements of process arrays. At most, what is taught by Figure 12 is that certain elements of process arrays according to Kellogg et al. may have a rectangular shape. Applicants maintain the position that Kellogg et al. fail to teach a sample processing device that includes

Amendment and Response

Page 11 of 14

Serial No.: 10/808,124

Confirmation No.: 4531

Filed: 24 March 2004

For: MULTI-FORMAT SAMPLE PROCESSING DEVICES, METHODS AND SYSTEMS

input chambers and output chambers (or output chambers, as recited in claim 17) that are arranged in a rectilinear grid array, as recited in claims 1, 6, 10, 13, and 17.

For at least the above reasons, it is submitted that claims 1, 6, 10, 13, and 17 are not anticipated by Kellogg et al. It is further submitted that dependent claims 2-5, 7-9, 11, 12, 14-16, 18, and 19 are patentable for the reasons presented above with respect to independent claims 1, 6, 10, 13, and 17. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Claims 1-19 were also rejected under 35 U.S.C. §102(b) as being anticipated by WO 99/58245 or EP 0693560. These rejections are respectfully traversed.

WO 99/58245

WO 99/58245 (hereinafter "WO '245") discloses a microfluidic device adapted such that the flow of fluids within the device is controlled by different surfaces of the device having different surface characteristics (WO '245, abstract). The microfluidic device is preferably circular and adapted for rotation about its axis (WO '245, page 5, lines 15-16). Further, there is no teaching of any other shape of microfluidic device in WO '245 other than circular. Thus, WO '245 fails to teach a rectangular body as recited in claims 1-19.

A mask, such as shown in Figure 1 of WO '245 may be used to form arrays of hydrophilic spots on a hydrophobic surface, such as shown in Figure 2 (WO '245, page 8, lines 22-24 and page 9, lines 4-5). When a suitable force is applied, a fluid may be caused to pass from spot to spot (WO '245, page 9, lines 7-9). With respect to Figures 6 and 7, described in the passage at page 10, line 25 through page 11, line 19 and cited in support of this rejection, element 20 (identified in the final Office Action as the sample inlet) is, in fact, an inner annular channel for reagent, and the sample inlets (e.g., input chambers) are indicated at elements 22 (WO '245, page 10, lines 25-26 and 29). Nonetheless, neither the annular reagent channel 20 nor the sample inlets 22 are arranged in a rectilinear grid array. Likewise, the waste channels 19 (e.g., output

Amendment and Response

Page 12 of 14

Serial No.: 10/808,124

Confirmation No.: 4531

Filed: 24 March 2004

For: MULTI-FORMAT SAMPLE PROCESSING DEVICES, METHODS AND SYSTEMS

chambers) which are arranged about the circumference of the circular fluidic device are also not arranged in a rectilinear grid array. That is, while the hydrophilic 14 and hydrophobic 15 areas may be provided according to Figure 2, neither the sample inlet nor the waste channel is arranged in a rectilinear grid array.

Further, the arrays of WO '245 include spots of hydrophilic and hydrophobic areas, wherein a force (e.g., centrifugal force) is required to overcome the boundary between a hydrophilic and hydrophobic surface area and move the fluid along the arrays of the device. That is, the input chamber, the output chamber, the primary process chamber, and, where claimed, the secondary process chamber, of each process array are not interconnected as recited in claims 1-19.

For at least the foregoing reasons, Applicants respectfully submit that WO '245 does not anticipate claims 1-19.

EP 0693560

EP 0693560 (hereinafter "EP '560") teaches a method and test unit for carrying out an immunoassay or an integrated nucleic acid amplification and nucleic acid assay (EP '560, abstract). The test unit includes sample, reagent, and waste chambers, wherein the sample and reagent flow is controlled by centrifugal force provided when the test unit is placed in a rotating automated test instrument (EP '560, abstract). It is asserted that EP '560 teaches rectangular test units "comprising wells (50, 60, 62) in fluidic connection [which] have been read on the claimed 'input', 'primary process chamber' and 'output chamber' respectively" (final Office Action, page 4, lines 1-4). Applicants disagree that EP '560 teaches rectangular test units and additionally point out that no portion of EP '560 is identified as teaching the features of input chambers and output chambers of process arrays of the plurality of process arrays as recited in claims 1-19.

First, it is submitted that the test units taught by EP '560 do not include a rectangular body comprising four identifiable corners at the junctions of four identifiable sides and two major surfaces as recited in claims 1-19. The test units of EP '560 include a square (outer) end and a

Amendment and Response

Page 13 of 14

Serial No.: 10/808,124

Confirmation No.: 4531

Filed: 24 March 2004

For: MULTI-FORMAT SAMPLE PROCESSING DEVICES, METHODS AND SYSTEMS

rounded (inner) end (EP '560, col. 8, lines 13-15; see also, Figures 4, 5, 6A, 7A, 8A, 9A, 10A, 11A, 12A, 13A, and 14A). The test units of EP '560 having one square end and one rounded end prevent the units from having four identifiable corners, and no embodiment of the test units of EP '560 teach anything other than a test unit having one square end and one rounded end. Thus EP '560 does not disclose include a rectangular body comprising four identifiable corners at the junctions of four identifiable sides and two major surfaces, as recited in claims 1-19.

In addition, while it is indicated in the final Office Action that elements of the test unit of EP '560 are considered to read on the claimed "input," "primary process chamber" and "output chamber" (elements 50, 60, and 62, respectively), the test units of EP '560 include a single process array including chambers 50, 60, 62, 64 and 66 interconnected by channels in a "linear arrangement" so that "centrifugal force can be applied by the apparatus of Figs. 1-3 to properly sequence the flow of the liquid biological sample and liquid reagents through the test unit" (EP '560, col. 12, lines 37-42; Figures 4, 5, 6A, 7A, 8A, 9A, 10A, 11A, 12A, 13A, and 14A). Because of that arrangement of chambers of a process array provided on the test units of EP '560, it is submitted that EP '560 does not teach a sample processing device including a rectangular body and a plurality of process arrays *located within the body*, each of the process arrays including an input chamber, an output chamber, and a primary process chamber located between the input chamber and the output chamber, wherein the primary process chambers are arranged in a circular arc, and further wherein the sample processing device includes output chambers arranged in a rectilinear grid array (claims 1, 6, 10, 13, and 17) and the input chambers are arranged in a rectilinear grid array (claims 1, 6, 10, and 13).

For at least the foregoing reasons, neither WO '245 nor EP '560 anticipate claims 1-19. Thus, reconsideration and withdrawal of the rejections of claims 1-19 as anticipated by either WO 99/58245 or EP 0 693 560 are respectfully requested.

Amendment and Response

Page 14 of 14

Serial No.: 10/808,124

Confirmation No.: 4531

Filed: 24 March 2004

For: MULTI-FORMAT SAMPLE PROCESSING DEVICES, METHODS AND SYSTEMS**New Claims 20-24**

Claims 20-24 have been presented to provide further protection of Applicants' invention as disclosed in the specification.

Entry, consideration, and allowance of these new claims are respectfully requested

Summary

It is respectfully submitted that the pending claims 1-24 are in condition for allowance and notification to that effect is respectfully requested.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

Mueeting, Raasch & Gebhardt, P.A.

P.O. Box 581415

Minneapolis, MN 55458-1415

Phone: (612) 305-1220

Facsimile: (612) 305-1228

15 JAN 2008

Date

By: 

Kevin W. Raasch

Reg. No. 35,651

Direct Dial (612) 305-1218

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 15th day of January, 2008, at 1:52pm (Central Time).

By: Name: Sara E. Nigant